

REMARKS

AMENDMENTS TO THE CLAIMS

Claims 1 and 3 have been amended to recite that the melt crystallization step d) yields a fraction d1) of purified lactide having a total lactide content of 99-99.9% and at least a first residual fraction d2) having a lactide content comprised between 35 and 80%. Support for these amendments can be found page 31, lines 3-9 and 15-19 of the present specification.

The Examiner required clarification as to how it is possible to have a 15% m-lactide impurity from a composition which starts with less than 1% m-lactide impurity. Step e) of amended claims 1 and 3 recite the at least first residual fraction of step d2), clearly supporting that the aqueous treatment defined in the step is applied to the residual fraction d2) and not to the purified fraction d1) as disclosed in Yamaguchi (cf. Figures 1 and 2 below). The step e3) of amended claims 1 and 3 specify that the prepurified lactide is obtained from the at least first residual fraction d2). Basis for these amendments is found on page 31, lines 10-19 and Figure 1, 601 (pure lactide fraction d1), 602 (residual fraction d2), 700, 800, and 900 defining the aqueous treatment e) applied to the residual fraction through connecting line 602).

Dependent claims 10, 26 and 48-52 are objected to because the Examiner states it is unclear how the m-lactide content can be above 1% when claim 1 recites that it is less than 1%. Dependent claims 10, 26 and 48-52 have been amended to specify that the content of meso-lactide comprised between 0 and 15% refers to the prepurified lactide fraction “obtained from the aqueous treatment e) of the residual fractions d2)”, which is different from the pure lactide fraction d1) as defined in claims 1 and 3 that comprises less than 1% meso-lactide.

PROCESS OF THE CLAIMED INVENTION

The processes of claims 1 and 3 recite a crude lactide obtained from a solution of lactic acid through steps a) to c) that is treated by melt crystallization in step d) to yield:

- d1) a fraction of purified lactide comprising a total lactide content of 99-99.9% and a meso-lactide content of less than 1%, and
- d2) at least one residual fraction comprising between 35 and 80% of lactide.

The at least first lactide poor residual fraction of d2), not the lactide rich purified lactide fraction of d1), is further purified by an aqueous treatment e), e1)-e2) to yield a prepurified lactide fraction obtained from said at least first residual fraction of step d2).

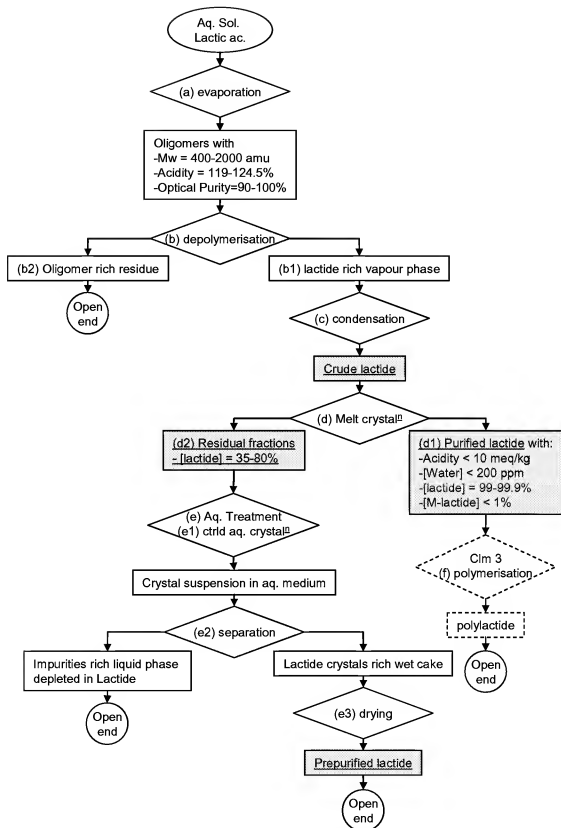


Figure 1: Flowchart illustrating the process steps called for in claims 1 and 3 dashed lines).

103(A) REJECTION IN VIEW OF YAMAGUCHI (US 5,502,315) AND O'BRIEN (US 6,301,218)

Claims 1, 3, 5, 6, 9, 10, 21, 22, 25, 26, 44, 45, 48, 49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi (US 5502215) in view of O'Brien (US 6310218). As illustrated in Figure 2 below, the lactide purification process of Yamaguchi is different from the claimed process. In Yamaguchi, crude lactide is obtained through the steps disclosed in column 4, lines 44-52 (not shown in Figure 2 below), and examples of compositions are disclosed in Tables 3, 6, 8, 12, 15, 17, and 18. The crude lactide thus obtained is then fed to a reaction vessel and mixed with water. The mixture is then immediately cooled and left at a given temperature for a prescribed period of time to obtain,

- a purified lactide fraction [1], rich in lactides but poor in meso-lactide (0.5-2.5%) (cf. Tables 4, 7, 9, 13, 16, and 19) and,
- a first residual fraction [1] comprising impurities and hydrolysed meso-lactide (cf. Yamaguchi, column 3, lines 16-29 and column 7, lines 29-32).

Yamaguchi further teaches that the purified lactide fraction [1] may be re-purified by contacting it with a solvent (cf. column 3, lines 64-column 4, line 2) to yield

- a re-purified lactide fraction, with a content in meso-lactide <0.3% (cf. Tables 10, 14, 20), and
- a second residual fraction [2].

The second residual fraction [2], referred to as "mother liquid" by Yamaguchi (cf. column 12, line 49), may be concentrated by separating the remaining lactide in the form of crystals to yield a crude lactide fraction [2], which is then contacted with a solvent (e.g., acetone) to yield:

- a purified fraction [2] comprising a low amount of meso-lactide ($\leq 0.3\%$, cf. Table 11), and
- a residual fraction [3] comprising all the impurities removed from the various purified and re-purified fractions.

Referring to Figure 2, Yamaguchi teaches to treat crude lactide with a first purification process (viz., mixing crude lactide with water and cooling the mixture as explained above) to yield two fractions:

- purified lactide [1], and

- a residual fraction [1].

Yamaguchi discards any further purification step of the residual fraction [1] of the first purification stage. This is logical since mixing the crude lactide with water yields partial hydrolysis of meso-lactide, which renders it unsuitable for any further purification stages (cf. US5,502,215, col.7, 1.4-5). Yamaguchi teaches applying a second purification step to said purified lactide [1] fraction, not to the residual fraction [1] thereof, which contains hydrolysed meso-lactide to yield:

- re-purified lactide of higher purity than the purified lactide [1] (cf. Table 1 of our response filed on February 4, 2008), and
- a residual fraction [2] of high purity (though lower than both purified [1] and re-purified lactide fractions) since the starting product of the second purification step is the lactide rich purified lactide [1].

Only at this stage is the residual fraction [2] of the re-purification stage further purified by first concentrating said residual fraction [2] to yield a crude lactide [2], which is then dissolved in a solvent, and thus re-crystallising lactide to yield purified lactide [2] (= solvent crystallization). The residual fraction [2] of the re-purification stage is already quite pure since the starting material is purified lactide [1], which already shows a very high degree of purity (cf. Tables 4, 7, 9, 13, 16, 18 in Yamaguchi). This is a completely different situation as the one contemplated in amended claims 1 and 3 for the following reasons.

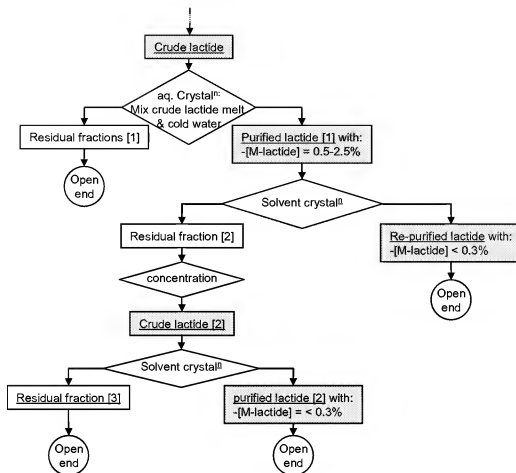


Figure 2: Flowchart illustrating the process steps disclosed in Yamaguchi (US 5,502,215)

Referring to Figure 1 supra, the process recited in claims 1 and 3 also comprise a first purification step d) of crude lactide (by melt crystallization) to yield a:

- purified lactide fraction d1), and
- a residual fraction d2) comprising 35-80% lactide.

The subject matter of claims 1 and 3 differ completely from the process taught by Yamaguchi. In the claimed invention, unlike Yamaguchi, the lactide poor residual fraction d2), not the purified fraction d1), is further purified. This is shown when comparing Figure 1 illustrating the present process with Figure 2 illustrating Yamaguchi's process. Yamaguchi teaches the further purification of residual fraction [2], but this is not comparable with the residual fraction d2) as defined in claims 1 and 3 because the residual fraction [2] of Yamaguchi has a

much higher lactide content than the residual fraction d2) of the claimed invention. Furthermore, the residual fraction [2] in Yamaguchi is further purified by mixing a solvent with crude lactide [2] obtained by concentrating the residual fraction [2]. The residual fraction d2) of the present invention is further purified by mixing it with water.

Both processes discussed above comprise the production of crude lactide which has comparable compositions, the crude lactide undergoing in both cases a purification step to yield a purified fraction and a residual fraction. However, they differ in that in Yamaguchi, the purified lactide [1] thus obtained is further purified, while there is no further purification step of the purified fraction d1) in the claimed invention (it is not discarded, but it is not essential to the invention). On the other hand, what is essential to the present invention is that the residual fraction d2) is further purified to finally yield a pre-purified lactide fraction. No further purification step of the residual fraction [1] is disclosed in Yamaguchi, for the simple reason that it contains too high levels of hydrolysed meso-lactide to allow further purification thereof.

For the reasons presented above, it is respectfully submitted that the subject matter of claims 1 and 3 as amended is not obvious, regardless of whether or not the aqueous treatment applied to the crude lactide in Yamaguchi is considered as melt crystallization as called for in claims 1 and 3. The aqueous treatment disclosed in Yamaguchi corresponds to “quench crystallization” in contrast with “ordinary crystallization” as referred to in Yamaguchi (column 2, line 21), which corresponds to “melt crystallization” as called for in present claims 1 and 3, further distinguishing the present invention from the disclosure of Yamaguchi.

CLAIM 3

Claim 3 further recites the step f) of polymerization of the lactide to polylactide (cf. Figure 1 supra, dashed boxes). The arguments set forth with respect to claim 1 apply to claim 3. The subject matter of present claim 3 is inventive over the teaching of Yamaguchi (US5,502,215) taken alone or in combination with O'Brien (US6,310,218 and US5,521,278).

CLAIMS 10, 26, 48-52

Claims 10 and 48-52 depend on claim 1, and claim 26 depends on claim 3. The claims have been amended to specify that the prepurified lactide “obtained from the aqueous treatment e) of the residual fractions d2)” contains 0 and 15% meso-lactide. This is compatible with the meso-

lactide content of less than 1% in the purified lactide d1) fraction as recited in claims 1 and 3 on which they depend, because as can be clearly seen in Figure 1 supra, prepurified lactide is not obtained from purification of the purified lactide d1), but from the residual fraction d2).

CLAIMS 7, 8, 11-14, 23, 24, 36, 37, 39-43, 46, 47, 50 and 51

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi and O'Brien in further view of O'Brien (US5521278). Claims 7, 8, 13, 14, 23, 24, 36, 37, 39-43, 46, 47, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi and O'Brien '218 in further view of Gruber (US6326458). The claims depend on patentable independent claims 1 and 3 and are allowable for the reasons set forth above.

No additional fees are seen to be required. If any additional fees are due, however, the Commissioner is authorized to charge Deposit Account No. 50-1482, in the name of Carlson, Gaskey & Olds, P.C., for any additional fees or credit the account for any overpayment. Therefore, favorable reconsideration and allowance of this application is respectfully requested.

Respectfully Submitted,

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